



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/731,500

12/09/2003

David M. Hardin JR.

10000/227

4634

7590 07/08/2009
Brinks Hofer Gilson & Lione
P.O. Box 10395
Chicago, IL 60610

EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

07/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,500	Applicant(s) HARDIN ET AL.	
	Examiner HELEN NGUYEN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-24, 26-68, 70-78 and 80-107 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 17, 22-24, 30-52, 64-68, 71, 76-78 and 84-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16, 18-21, 26-29, 53-63, 70, 72-75 and 80-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the response filed 3/12/2009. Claims 1-14, 16-24, 26-68, 70-78, and 80-107 are currently pending. Claims 13-14, 17, 22-24, 30-52, 64-68, 71, 76-78, and 84-107 are withdrawn as drawn to a nonelected species/invention. **Claims 1-12, 16, 18-21, 26-29, 53-63, 70, 72-75, and 80-83** remain under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-2, 7-11, 20, 29, 53-54, 59-62, 74, and 83** are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (US Pat No. 4249541) in view of Reeves et al (US Pat No. 7056293).

4. In regards to **Claim 1**, Pratt discloses a medical apparatus comprising:

a needle 22 comprising an elongate flexible shaft 40 having a proximal end, a distal end, and an inner lumen 52 extending from said proximal end to said distal end, best seen in Figure 1, the shaft comprising a length and flexibility sufficient to extend through a working channel of an endoscope 10 and engage a target tissue located beyond a distal end of the endoscope, best seen in Figure 2 and 5;

Art Unit: 3736

a stylet 24 having a proximal end and a distal end, wherein said stylet is adapted to be inserted into and withdrawn from said inner lumen of said needle with at least a portion of said stylet capable of and thus adapted to plug said inner lumen of said needle when a cytology sample is cut (Col.3: 61-65).

5. However, Pratt does not teach a cytology collection device adapted to be inserted into said inner lumen of said needle and extend beyond the distal end of the needle in order to collect said cytology sample. However, Pratt does teach the use of suction and syringe 98 to collect a cytology sample (Col.4: 1-15).

6. Reeves et al disclose an analogous medical device comprising: a needle 12 having a proximal end, a distal end, and an inner lumen extending from said proximal end to said distal end, best seen in Figure 3, a stylet 16 having a proximal end and a distal end, wherein said stylet is adapted to be inserted into and withdrawn from said inner lumen of said needle with at least a portion of said stylet adapted to plug said inner lumen of said needle when a cytology sample is cut (Col.3: 27-35); and a cytology collection device 48 having a proximal end and a distal end, wherein said cytology collection device is adapted to be inserted into said inner lumen of said needle when said stylet is withdrawn from the inner lumen of said needle, with said distal end of said cytology collection device adapted to extend beyond the distal end of said needle in order to collect said cytology sample, best seen in Figure 2 (Col.4: 45-55).

7. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Pratt such that a cytology collection device is adapted to be inserted into said inner lumen of said needle and extend beyond the distal end of

Art Unit: 3736

the needle as taught by Reeves et al in order to offer an effective alternative method to collect said cytology sample.

8. In regards to **Claims 2**, Reeves et al disclose said cytology collection device 48 comprises an elongate member having a proximal end, a distal end, and a plurality of bristles (Col.4: 22-28), the distal end being adapted to plug said inner lumen of said needle after the cytology sample has been collected.

9. In regards to **Claim 7**, Reeves et al disclose the distal end of the elongate member is adapted to be retracted within the inner lumen of said needle after collecting said cytology sample.

10. In regards to **Claims 8 and 59**, Pratt discloses said needle 22 is made of one ore more of steel and metal (Col.3: 12-13).

11. In regards to **Claims 9, 54, and 60**, Reeves et al disclose said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer (Col.4: 25-27).

12. In regards to **Claims 10 and 61**, Pratt discloses said needle 22 is adapted to provide suction (Col.4: 1-2).

Art Unit: 3736

13. In regards to **Claims 11 and 62**, Reeves et al disclose a handle 20 which is adapted to provide axial movement of said cytology collection device 48 and said needle 12, best seen in Figure 3.

14. In regards to **Claims 20 and 74**, Pratt discloses said stylet 24 is a solid rod used to plug said needle 22. Reeves et al also disclose said stylet 16 is a solid rod used to plug said needle 12.

15. In regards to **Claims 29 and 83**, Reeves et al disclose an outer surface of said stylet 16 has a first diameter and an inner surface of said needle 12 has a second diameter slightly larger than said first diameter, wherein said outer surface of said stylet is adapted to contact said inner surface of said needle to plug said inner lumen of said needle while said cytology sample is cut (Col.3: 31-34). Pratt also discloses the same.

16. In regards to **Claim 53**, Pratt discloses a method for collecting a cytology sample from a mammalian body comprising:

providing an apparatus comprising: a needle 22 comprising an elongate flexible shaft 40 having a proximal end, a distal end, and an inner lumen 52 extending from said proximal end to said distal end, best seen in Figure 1, the shaft comprising a length and flexibility sufficient to extend through a working channel of an endoscope 10 and engage a target tissue located beyond a distal end of the endoscope, best seen in Figure 2 and 5; a stylet 24 having a proximal end and a distal end;

Art Unit: 3736

inserting said stylet into said inner lumen of said needle, wherein at least a portion of said stylet plugs said inner lumen of said needle (Col.3: 50-54);

cutting an area within said mammalian body (Col.3: 63-65);

withdrawing said stylet from said inner lumen of said needle (Col.3: 67-68);

collecting a cytology sample (Col.4: 1-2).

17. However, Pratt does not disclose the apparatus having a cytology collection device inserted into the inner lumen of said needle to collect the cytology sample. Reeves et al disclose an analogous medical device comprising: a needle 12 having a proximal end, a distal end, and an inner lumen extending from said proximal end to said distal end; a stylet 16 having a proximal end and a distal end; a cytology collection device 48 having a proximal end and a distal end for cytology collection.

18. Reeves et al also disclose a method of collecting a cytology sample from a mammalian body comprising:

inserting said stylet into said inner lumen of said needle, wherein at least a portion of said stylet plugs said inner lumen of said needle (Col.3: 31-34);

withdrawing said stylet from said inner lumen of said needle (Col. 4: 45-47);

inserting said cytology collection device into said inner lumen of said needle so that said distal end of said cytology collection device extends beyond the distal end of said needle (Col.4: 54-55);

collecting said cytology sample from said mammalian body using said cytology collection device (Col.4: 55);

Art Unit: 3736

retracting said distal end of said cytology collection device into said inner lumen of said needle, wherein at least a portion of the distal end of the cytology collection device plugs said inner lumen of said needle (Col.56-60).

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Pratt such that a cytology collection device is adapted to be inserted into said inner lumen of said needle and extend beyond the distal end of the needle as taught by Reeves et al in order to offer an effective alternative method to collect said cytology sample.

20. **Claims 3-6, 21, 25-28, 55-58, 75, and 80-82** are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt in view of Reeves et al, further in view of Wang (US Pat No. 4966162).

21. In regard to **Claims 3-6 and 55-58**, Pratt in combination with Reeves et al disclose the cytology collection device 48 above but do not explicitly disclose the structure and material of its distal end or the structure and material of its elongate member. Wang discloses an analogous cytology collection device 176, 230 having a distal end terminating in a loop 232 and comprises a wire 170 twisted around a plurality of bristles 178, best seen in Figures 6 and 11. Wang also discloses said cytology collection device made of steel (Col.6: 10-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the cytology collection device of Pratt as modified by Reeves et al to have a distal end terminating a loop and also comprising a wire twisted around a plurality of bristles and said distal end and said

Art Unit: 3736

wire made of steel as taught by Wang as an effective configuration and make of said cytology collection device for the purpose of sampling.

22. In regard to **Claims 21 and 75**, Pratt in combination with Reeves et al disclose the stylet 24 above but do not specify the material. Wang discloses an analogous device made of steel (Col.8: 35-36) as an effective material used for tissue sampling. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stylet of Pratt as modified by Reeves et al out of steel as taught by Wang as a desirable material used for such sampling device.

23. In regard to **Claims 26-27 and 80-81**, Pratt in combination with Reeves et al disclose the stylet 24 above but do not disclose said style adapted to cut said cytology sample. Wang teaches an analogous style 140 having a sharp distal end 174, best seen in Figure 3 and 6 to cut a cytology sample allowing greater range of sampling (Col.6: 47-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stylet of Pratt as modified by Reeves et al with a sharp distal end adapted to cut a cytology sample as taught by Wang to allow penetration of cysts and other tissue for a greater sampling range.

24. In regards to **Claims 28 and 82**, Pratt in combination with Reeves et al and Wang disclose said distal end of said stylet 24 is adapted to extend beyond the distal end of said needle 22.

Art Unit: 3736

25. **Claims 12 and 63** is rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt in view of Reeves et al, further in view of Rabiner et al (US Pat No. 6579279).

26. Pratt and Reeves et al disclose the handle 20 above but do not disclose said handle comprising an inner handle member, a first outer handle member, and an elongate sheath.

Rabiner et al disclose an analogous device comprising an inner handle member 40 having a proximal end and a distal end; a first outer handle member 42 slideably disposed on the inner handle member; and an elongate sheath 26 attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen to allow a catheter 29 to be disposed in the sheath lumen, best seen in Figures 1-2. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the handle of Pratt as modified by Reeves et al to include an inner handle member, a first outer handle member, and an elongate sheath in the manner taught by Rabiner et al an effective arrangement that allows locking and relative movement and rotation of said handle members as well as the component disposed within the sheath, wherein in use it would be obvious to place the needle within the sheath lumen.

27. **Claims 16, 18-19, 70, and 72-73** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Ishiguro (US Pat No. 6108439).

28. In regards to **Claims 16 and 70**, Pratt in combination with Reeves et al disclose the device above including an endoscope 10 including a viewing tube 90 but do not disclose the use of an ultrasound transducer to determine the position. Ishiguro teaches an ultrasound transducer

Art Unit: 3736

10 that emits ultrasound waves used to determine position (Col.11: 61-67; Col.12: 1-5).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made modify the endoscope of Pratt as modified by Reeves et al to include an ultrasound transducer as taught by Ishiguro as an effective means to determine the position of said cytology collection device within the body, wherein the needle and the cytology collection device are simultaneously disposed through a working channel of the endoscope.

29. In regards to **Claims 18 and 72**, Pratt in combination with Reeves et al and Ishiguro disclose said cytology collection device 48 comprises an elongate member having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves capable of reflecting off said plurality of bristles.

30. In regards to **Claims 19 and 73**, Pratt in combination with Reeves et al disclose said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer (Col.4; 25-27).

Response to Arguments

31. Applicant's arguments filed 3/12/2009 have been fully considered but they are not persuasive. Applicant contends that Reeves et al teach away from the present invention because the needle of Reeves et al is not adapted to extend through an endoscope. However, it is noted that Reeves et al have merely been relied upon to teach the cytology collection device 48 which is inserted into an analogous combination needle and stylet structure. Reeves et al have not been

Art Unit: 3736

relied upon to teach the flexible needle, which is already taught by Pratt. It is reasonably envisioned that the cytology collection device of Reeves et al (i.e. cytology brush, which is similar to Applicant's own cytology collection device) would be completely operable with the flexible needle of Pratt. Thus, Reeves et al still constitute analogous art as reasonably pertaining at least to Applicant's problem solving area, namely, collecting a cytology sample from a mammalian body. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Therefore, because Pratt already teaches the use of suction and a syringe to collect a cytology sample, it would have been obvious to substitute the collection means of Pratt with a cytology collection device as taught by Reeves et al to effectively and predictably collect said cytology sample as elaborated above.

Conclusion

32. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3736

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340.

The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736